



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

April 30, 2002

Kai Hansjurgens
Hako-Med
537 Cummins St.
Honolulu, HI 96814

Dear Mr. Hansjurgens:

Your petition requesting the Food and Drug Administration to issue an exemption of any connector in a lead having a conductive connection to a patient shall be constructed that no conductive connection should be possible hazardous voltages, was received by this office on 04/30/02. It was assigned docket number 02P-0187/CP 1 and it was filed on 04/30/02. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Helen K. Harris
Dockets Management Branch

02P-0187

ACK1